REMARKS

The Office Action of March 30, 2004, has been received and reviewed. Claims 1, 3, 8, 9, 11, 14-19 and 29-33 are pending in the application and all pending claims stand rejected. Claims 1, 3, 8, 14, 17-19, 30 and 33 have been amended and new claim 36 has been added as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is requested.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claim 30 stands rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking compliance with the enablement requirement. Applicants respectfully traverse the rejection.

Specifically, the Office Action indicated that the specification "does not reasonably provide enablement for such a method using any means (i.e., any DNA)... Claim 30 [is] so broad as to encompass the use of any DNA having the capability to encode any protein and isolated from any source ..." (Office Action, pages 2-3). However, as stated in the MPEP "35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language 'shall be construed to cover the corresponding structure ... described in the specification." (M.P.E.P. § 2181, page 2100-223). The MPEP further states "the 'means or step plus function' limitation should be interpreted in a manner consistent with the specification disclosure." (*Id.* at § 2182). Thus, claim 30 is not directed to "any DNA" as asserted in the Office Action, but rather is defined by the corresponding structure providing the function of enhancing septation and fragmentation disclosed on pages 4 and 5 of the as-filed specification. Thus, one of ordinary skill in the art would be able to make and use claim 30 without undue experimentation.

Reconsideration and withdrawal of the enablement rejection of claim 30 are requested.

Written Description

Claim 30 stands rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Applicants respectfully traverse the rejection.

The Office Action asserted that "the genus of the 'means' is a large variable genus with the potentiality of having different structures. Therefore, many structurally unrelated 'means' (i.e., DNAs) are encompassed within the scope of the these claims." (Office Action at page 5). However, "the 'means or step plus function' limitation should be interpreted in a manner consistent with the specification disclosure." (M.P.E.P. at § 2182). Thus, since pages 4 and 5 of the as-filed specification describe a structure that correlates with the function of enhancing septation and fragmentation, one of ordinary skill in the art would conclude that the inventors were in possession of claim 30.

Reconsideration and withdrawal of the written description rejection of claim 30 are requested.

Rejections under 35 U.S.C. § 102

Claims 1, 3, 8-9, 11 and 14-15 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kawamoto et al. Applicants respectfully traverse the rejections.

The Office Action asserted

> Kawamoto et al. disclose a strain of Streptomyces NRRL B2682 which sporulates in liquid medium but produces profuse branches and does not sporulate in rich medium. Kawamoto et al. also disclose that the very same bacterium forms septum only after transformation with *ssgA*. It is clear from this information that such a strain was not producing detectable levels of SsgA endogenously before transformation, because if detectable levels of SsgA was being produced by said strain, it would have formed septum and not spores or filaments. Furthermore it is clear from the figure 2 panels that said strain of Kawamoto et al. did not produce endogenous SsgA since there is no signal in the first 16 hours of incubation after transformation. This clearly shows that there was no endogenous synthesis of SsgA. Examiner also takes the position that such a characteristic was inherently in that strain.

(Office Action, pages 7-8).

However, Kawamoto et al. does not expressly or inherently disclose each and every element of amended claim 1 as required for anticipation. For instance, Kawamoto et al. does not disclose a method for producing a recombinant Streptomyces comprising providing a Streptomyces with an expressible polynucleotide encoding a **heterologous** SsgA as recited in amended claim 1. Rather, Kawamoto et al. is limited to a *ssgA* cloned from *Streptomyces griseus*

and used to transform the *Streptomyces griseus* B2682 strain or mutants of *Streptomyces griseus* which does not result in a heterologous SsgA (*See*, Kawamoto et al., Table 1).

Kawamoto et al. does not disclose a method for producing a recombinant Streptomyces comprising providing a Streptomyces bacterium lacking detectable endogenous SsgA during submerged culture as recited in amended claim 1. *Streptomyces griseus* strain B2682 does express SsgA during submerged culture as disclosed in Fig. 2(a) which depicts *Streptomyces griseus* expressing SsgA in DMCY and DM1 media. (*See*, *Id.* at Fig. 2(a)). Kawamoto et al. further indicates that *Streptomyces griseus* "B2682 cells grown to mid-exponential growth phase (for 18h) in DMCY were transferred to DM1 containing no casein hydrolysate. **Significant expression of SsgA** was detected 1h after shift-down." (*Id.* at page 1082) (emphasis added). Further, as Kawamoto et al. indicates that *Streptomyces griseus* strain B2682 sporulates during submerged culture (*See*, *Id.* at page 1077) and the formation of septum is an obligatory step for sporulation (*See*, Kwak et al., page 5092, submitted herewith in an Information Disclosure Statement), sporulation is not possible without septum formation.

Accordingly, the statement in the Office Action that "because if detectable levels of SsgA was being produced by said strain [i.e., B2682], it would have formed septum and not spores or filaments" cannot establish that strain B2682 does not produce endogenous SsgA because the fact that strain B2682 sporulates in submerged culture is evidence of the formation of the septum. Thus, Kawamoto et al. cannot expressly or inherently disclose each and every element of amended claim 1.

Claims 3, 8-9, 11 and 14-15 are not anticipated, at the very least, as depending from novel independent claim 1.

With further regard to claim 8, it cannot be anticipated since Kawamoto et al. does not disclose an expressible polynucleotide being integrated into the genome of the bacterium.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 3, 8-9, 11 and 14-15 are requested.

Rejections under 35 U.S.C. § 103

Claims 16-19 and 30-33 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Kawamoto et al. as applied to claims 1, 3, 8-9, 11 and 14-15, and further in

view of the common knowledge in the art for making recombinant bacterium and expressing heterologous proteins using the same. Applicants respectfully traverse the rejections.

Since dependent claims 16-19 include the elements of independent claim 1 and a *prima facie* case of obviousness cannot be established with regard to independent claim 1, a *prima facie* case of obviousness also cannot be established with regard to any of dependent claims 16-19.

Turning to independent claims 30 and 33, a *prima facie* case of obviousness cannot be established since Kawamoto et al. does not alone or in view of the common knowledge in the art for making recombinant bacterium teach or suggest each and every element of claim 30 or 33.

Each of claims 30 and 33 includes the element of transforming an Actinomycete bacterium lacking a detectable endogenous SsgA. As previously established herein with regard to the asserted anticipation rejections, Kawamoto et al. does not teach or suggest an Actinomycete bacterium lacking detectable endogenous SsgA, but rather discloses an Actinomycete bacterium having "**significant expression of SsgA** [] detected 1h after shift-down." (Kawamoto et al. at page 1082) (emphasis added).

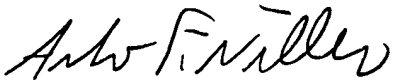
Since dependent claims 31-32 include the elements of independent claim 30 and a *prima facie* case of obviousness cannot be established with regard to independent claim 30, a *prima facie* case of obviousness also cannot be established with regard to dependent claims 31-32.

Reconsideration and withdrawal of the obviousness rejections of claims 16-19 and 30-33 are requested.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the claims define patentable subject matter and a notice of allowance is requested. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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